



K071229

MAY 18 2007

## 5. 510(K) SUMMARY

<b>Prepared date</b>	April 20, 2007
<b>510(k) owner</b>	<b>SenoRx, Inc.</b> 11 Columbia Aliso Viejo, CA 92656 P. 949.362.4800 F. 949.362.3200
<b>Contact person</b>	Eben Gordon
<b>Device name</b>	SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy
<b>Common name</b>	Multi-lumen balloon source applicator
<b>Classification name</b>	Remote controlled radionuclide source applicator
<b>CFR classification</b>	21 CFR 892.5700 90 JAQ
<b>Predicate device</b>	Adjustable Multi-Catheter Source Applicator (K062241) MammoSite Radiation Therapy System (K041929)
<b>Decision date</b>	11/9/2006 (K062241) 8/26/2004 (K041929)
<b>Device description</b>	The SenoRad applicator consists of a multi-lumen catheter connected to an inflatable spherical balloon that can be attached to commercially available High Dose Rate remote afterloader equipment for passage of the radiation source delivery wire. Five radiation source wire lumens are provided; one central lumen located along the long axis of the applicator and four curved lumens symmetrically offset from the central lumen. The balloon is inflated to a 4 or 5 cm spherical shape by a controlled volume injection of physiological saline to approximately 32 or 55 ml, respectively.
<b>Indications for use</b>	The SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.
<b>Summary of substantial equivalence</b>	Extensive preclinical testing was conducted to evaluate and characterize the performance of the SenoRad Multi-Lumen Balloon Source Applicator. Preclinical studies conducted included in vitro laboratory studies to demonstrate that the SenoRad applicator performed as intended under simulated use conditions. Biocompatibility testing was performed to



demonstrate that the materials meet ISO 10993-1 requirements. The dosimetry of the SenoRad applicator was characterized. Based on these findings, it was concluded that the SenoRad applicator could deliver an equivalent radiation dose as the current brachytherapy applicators.

The SenoRad applicator has the following similarities to the previously cleared predicate devices: same indications for use; same intended use; same intended treatment site; same operating principle; same technological characteristics; equivalent dosimetric characteristics; and same sterilization method. The materials of construction vary in a manner that has no impact on device safety.

In summary, the SenoRad Multi-Lumen Balloon Source Applicator as described in this submission is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 22 2007

SenoRx, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1393 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K071229

Trade/Device Name: SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radionuclide applicator system  
Regulatory Class: II  
Product Code: JAQ  
Dated: May 2, 2007  
Received: May 3, 2007

Dear Mr. Job:

This letter corrects our substantially equivalent letter of May 18, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

**The safety and effectiveness of the SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.**

The Warning must be presented within a black box, and the font should be bold and the same size as any surrounding text. The Warning should be the first item in your list of warnings.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

#### 4. INDICATIONS FOR USE

510(k) Number (if known): K071229

Device Name: \_\_\_\_\_ SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy \_\_\_\_\_

Indications for Use:

The SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K071229

Page \_\_\_\_ of \_\_\_\_